



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/247,054	02/09/99	ANTONIOU	M CACO-0045

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MACKIEWICZ AND NORRIS  
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PHILADELPHIA PA 19103

HM22/0831

EXAMINER

BAKER, A

ART UNIT	PAPER NUMBER
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1632

DATE MAILED:

14  
08/31/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Advisory Action**Application No.  
**09/247,054**

Applicant(s)

**Antoniou et al.**

Examiner

**Anne-Marie Baker, Ph.D.**

Group Art Unit

**1632****THE PERIOD FOR RESPONSE: [check only a) or b)]**

- a) ☒ expires 4 months from the mailing date of the final rejection.
- b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Jul 17, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☒ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☒ will not be entered because:

- ☒ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: The proposed claim amendments would require a new ground of rejection under 35 U.S.C. 112, second paragraph, because Claims 5 and 16 recite improper Markush terminology because "or" is used between members of the Markush group where "and" is required.

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
Applicants argue that there is no motivation to combine the references cited in the 35 U.S.C. 103(a) rejection.  
Furthermore, Applicants argue that none of the cited references teaches or (cont. on attached sheet)
- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):  
Claims allowed: None  
Claims objected to: None  
Claims rejected: 1-21, 23, and 25

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.

- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_.

- ☐ Other

*Karen M. Hauda*  
**KAREN HAUDA**  
**PRIMARY EXAMINER**

Art Unit: 1632

**Advisory Action**

(cont.) suggests the use of episomal vectors comprising LCRs. Applicants appear to argue that the skilled artisan would only be motivated to use LCRs under circumstances where integration into a chromosome will occur. However, the stated motivation to use LCRs in episomal vectors to confer tissue-specific expression was based on the disclosure that the presence of an LCR resulted in tissue-specific expression of the linked gene. Although LCRs were used in the art to overcome position effects upon random integration of a heterologous construct, the property of conferring tissue-specific expression is a separate property that was known in the prior art. Episomal vectors were also well-known in the art. Since it would have been desirable to achieve tissue-specific expression using episomal vectors for gene transfer one would have been motivated to use a genetic element that confers tissue-restricted expression. The prior art discloses that LCRs have this property. Thus, one of skill in the art would have been motivated to incorporate LCR sequences into episomes of various types in order to make gene transfer vectors that confer tissue-specific expression of a heterologous gene. The fact that LCRs also have the property of insulating integrated DNA from position effects would not have detracted from its usefulness as a genetic element that directs tissue-restricted expression.

Thus, the claims remain rejected for reasons of record.